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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,006

11/14/2003

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14170-038006

7828

7590
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09/13/2007

EXAMINER

LEE, YUN HAENG NMN

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

09/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,006

Applicant(s)

SHARKEY ET AL.

Examiner

Yun H. Lee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 18, 19, 28, 29, 32 and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-5, 15, 22 and 25 is/are allowed.
- 6) ☒ Claim(s) 1, 6-10, 13, 14, 16, 17, 20, 21, 23, 24, 26, 27, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/14/2003, 3/31/2004, 10/27/2004, 4/17/2007, 6/18/2007.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-10, 13-17, 20-27 and 30-31 in the reply filed on 6/18/07 is acknowledged.
2. Claims 11, 12, 18, 19, 28, 29, 32 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/18/07.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 6-10, 13, 14, 16, 17, 20, 21, 23, 24, 26, 27, 30 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being

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unpatentable over claims 1-28 of copending Application No. 10/712,063. Although the conflicting claims are not identical, they are not patentably distinct from each other because either the claims in the present application are broader than the claims of the copending application, or the differences amount to obvious design choices with no criticality. For example, the limitation in claim 7 regarding the specific location where the electrode is positioned would have been considered a matter of obvious design choice because Applicant has not disclosed that positioning the electrode at a location selected from the group consisting of posterior medial inner, posterior lateral, anterior lateral and anterior medial wall of the annulus fibrosis solves any stated problem or is for any particular purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 9, 10, 13, 14, 16, 17, 20, 21, 26, 27 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Sluijter et al. (US Pat. No. 5,433,739).

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Regarding claim 9, Sluijter et al. disclose a method of manipulating a disc tissue at a selected location of an intervertebral disc, the disc having a nucleus pulposus, an annulus fibrosus, and an inner wall of the annulus fibrosus, the method comprising:

providing a catheter (1) having a radiofrequency electrode (2) at a distal region of the catheter and a proximal region (5) for externally guiding the distal region of the catheter within an intervertebral disc;

positioning the electrode at the selected location of the disc by twisting the proximal region of the catheter (col. 12 lines 59-60) and applying a sufficient force to advance at least a portion of the distal region of the catheter through the nucleus pulposus beyond a central region of the nucleus pulposus, which force is insufficient to puncture the annulus fibrosus (see figs. 1 and 2); and

delivering energy to the disc tissue at the selected location of the disc using the electrode (col. 5 lines 61-62).

Regarding claim 10, Sluijter et al. further discloses the delivering energy as raising the core temperature of the disc to 70 degrees Celsius (col. 8 lines 4-5).

Regarding claim 13, see the above discussion of claim 9.

Regarding claim 14, since adjacent simply means near or close, Examiner considers anywhere within the disc to be adjacent a portion of any portion of an inner wall of the disc.

Regarding claim 16, radiofrequency energy is one form of electromagnetic energy.

Regarding claim 17, see the above discussion of claim 10.

Regarding claim 20, Sluijter et al. further discloses advancing the electrode non-linearly within the intervertebral disc (see embodiment of fig. 6; col. 12 line 56 – col. 13 line 9).

Regarding claim 21, see the above discussion of claim 14.

Regarding claim 26, see the above discussion of claim 16.

Regarding claim 27, see the above discussion of claim 10.

Regarding claim 31, see the above discussions of claim 10 and 14.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sluijter et al. (US Pat. No. 5,433,739).

Regarding claim 8, Sluijter et al. disclose a method of manipulating a disc tissue of an intervertebral disc, the disc having a nucleus pulposus, an annulus fibrosus, and an inner wall of the annulus fibrosus, the method comprising:

providing a catheter (1) having a radiofrequency electrode (2) at a distal region of the catheter and a proximal region (5) for externally guiding (col. 12 lines 59-60) the distal region of the catheter within an intervertebral disc;

positioning the electrode at a selected location of the disc by applying a sufficient force to advance at least a portion of the distal region of the catheter through the nucleus pulposus beyond a central region of the nucleus pulposus, which force is insufficient to puncture the annulus fibrosus (fig. 1); and

delivering energy to the disc tissue at the selected location of the disc using the electrode (col. 2 lines 29-30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to repeat the above steps, since merely repeating a prior art method multiple times involves only routine skill in the art.

Allowable Subject Matter

9. Claims 2-5, 15, 22 and 25 are allowed.

10. The following is an examiner's statement of reasons for allowance: The prior art does not disclose or suggest a method comprising providing a catheter having a

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radiofrequency electrode at a distal region of the catheter and positioning the electrode at an inner wall of an annulus fibrosus or at a site of an annular fissure of the inner wall of a disc. The prior art also does not disclose or suggest a method comprising providing a catheter having a radiofrequency electrode at a distal region of the catheter and advancing the electrode non-linearly within an intervertebral disc beyond a central region of a nucleus pulposus of the disc to a selected location, wherein the electrode is advanced along a path of multiple degrees of curvature or wherein the selected location is at a site of an annular fissure of the inner wall of the disc.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 10-8.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766
September 9, 2007

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